Summary of the
***Ad Hoc* Transition Committee**
July 30, 1997

The *Ad Hoc* Transition Committee of the National Environmental Laboratory Accreditation Conference (NELAC) convened in working session on Wednesday, July 30, 1997, at 9:00 a.m. CDT. The working session was held during the NELAC Third Annual Meeting in Dallas, Texas. The session was chaired by Ms. Carol Batterton of the Texas Natural Resources Conservation Commission. A list of participants is given in Attachment A.

INTRODUCTORY REMARKS

Ms. Batterton opened the session by describing the two-fold purpose of the Committee: a) to anticipate issues and problems that might arise in the transition between establishment of NELAC consensus standards and the implementation of accreditation under the National Environmental Laboratory Accreditation Program (NELAP); and b) to develop a plan to assist the NELAP Director during this transitional period.

REVIEW OF THE *AD HOC* TRANSITION COMMITTEE REPORT TO NELAC

Ms. Batterton then initiated a review of the report of the *Ad Hoc* Transition Committee to NELAC. She highlighted four principal areas of concerns and the resulting recommendations of the Committee. In response to concerns that the first couple of NELAP-approved accrediting authorities might be inundated by laboratory applications, the Committee recommends that the nine states that have indicated an interest in immediate approval as accrediting authorities be accredited simultaneously as a group. In response to concerns that a small number of laboratories might gain some advantage by being the first to be NELAP-accredited by their respective accrediting authorities, the Committee recommends that the first group of laboratories seeking accreditation also be approved simultaneously. The Committee also recommends that laboratories be allowed to use their current proficiency test (PT) sample providers, with the frequency of testing agreeing with that prescribed in Chapter 2`of the NELAC Standards, until the Proficiency Testing Oversight Body can approve PT providers. Finally, the Committee recommends that all interested parties continue to provide comments and concerns related to implementation to the Committee.

Ms. Batterton then reviewed the anticipated dates for various phases of the transition process -- October 1997 for availability of NELAP applications; December 1, 1997 for submittal of those applications to NELAP; June 1998 for approval of the first group of accrediting authorities; and late 1998 or early 1999 for accreditation of the first group of laboratories.

Ms. Jeanne Murrain asked the attendees for input on what should be done after the initial group of accredited authorities is accredited. Should later applicants be reviewed on an individual basis or should they be amasses into a second group for review as a group? Most appeared to favor approval of accrediting authorities subsequent to the initial nine on a case-by-case basis. There was much discussion as to whether the nine initial applicants, if all were approved by NELAP,

would be able to handle all the laboratories which would in turn apply to them. Some thought that there would be no massive burden of laboratory applications because states would require considerable time to enact binding legislation. Many from the private sector said they would apply at their earliest possible convenience because to do otherwise would be financially devastating.

Much discussion was heard concerning the situation where a laboratory in a state that is not among the initial group seeking accreditation applies for and receives accreditation from a secondary accreditation authority. What happens when that laboratory's state becomes an accrediting authority? During the laboratory's re-approval process, does the laboratory have to go back to its home state? It was agreed that this is an issue warranting additional response from the Committee.

REVIEW OF THE RESULTS OF THE STATES' INTENT SURVEY

Ms. Batterton introduced Dr. Brokopp, who reviewed the findings of a survey sent to the states to gauge their interest/plans to apply to NELAP to be accrediting authorities. He indicated that all 50 states plus the Virgin Islands, the District of Columbia, the Marianas Islands, and Puerto Rico had responded to the survey. Most (40) indicated that their environmental laboratory certification programs intended to request NELAC recognition, that only nine states would request recognition immediately but that more than 40 would have requested recognition by late 1998, that most states will require legislative or statutory changes before requesting NELAC recognition, and that most will require changes to their regulations or administrative rules before NELAC recognition can be requested.

Considerable discussion was heard concerning states that intend to apply to be accrediting authorities but must put legislation in place to do so. The provisions in Chapter 6 of the NELAC Standards were discussed -- they allow a state with an established certification program to become an accrediting authority and still have two years to enact the necessary, pertinent legislation. There was general agreement from the attendees that this particular provision is not widely known and should be emphasized. Some states reported that they do not currently have statutes allowing them to grant or accept reciprocity.

Questions were then raised as to the intentions of the initial group of approved accrediting authorities. What would be their scopes of accreditation? Which laboratories (commercial, health, etc.) would first be engaged, and which programs (drinking water, etc.)? How many in-state and out-of-state laboratories would there be? Dr. Brokopp agreed that these were good questions for a second survey. When the idea of a second survey was mentioned, concern was expressed as to who would receive it and how it would be distributed. Several states indicated that they may eventually have multiple accrediting authorities (environmental, health, and agriculture). It was suggested that IAETL and others may have current lists of state certification programs to whom information should be sent. It was also suggested that all state NELAC contacts, NELAC Representatives and Delegates, and NELAC conference attendees serve to disseminate information regarding implementation of NELAP.

A question was asked as to who will review the accrediting authority applications. Ms. Mourrain replied that she, Mr. Ted Coopwood, and an assessment team comprised of state and/or federal officials, would perform the reviews. There was considerable concern as to whether this group could satisfactorily handle the first wave of applications. There was concern as well that more than the nine states identified in the intent survey might apply in the first group, given a higher "comfort level" with NELAP as a result of progress made at the Third Annual Meeting.

REVIEW OF APPLICATION PROCESS AND APPLICATION FOR ACCREDITING AUTHORITIES

Mr. John Anderson reviewed the draft application process and components of a draft of the application form that will eventually be used by states or federal agencies applying to become accrediting authorities. An accrediting authority will be required to complete an application and standardized checklist every two years. Only changes to an applicant's program will be identified on a renewal application. Any application must be complete and will be assessed for completeness independent of the technical evaluation. Three copies of the application will be required and citations will be required to assist the reviewers in locating all required components of the application. The application may be filed electronically but required signatures and certification statements must be submitted as originals.

The principal components of the draft application form include the name, address, and telephone number of the applicant; its statutes and regulations on laboratory accreditation; its policies, guidance documents, and standard operating procedures on accreditation operations; the names and qualifications of its contractors (assessor bodies) and terms of contractual agreements with those bodies; its quality system manual; its arrangements for appointing, training, and evaluating laboratory assessors; its conflict-of-interest disclosure program; the names and qualifications of its managers and technical staff; authorized signatories; and signed certification statement. The single area of greatest concern regarding the draft application form was Item #9, which requires a listing of laboratories applying for accreditation through a particular accrediting authority for the two years immediately preceding the application. A concern was expressed about any liability the accrediting authority might incur for laboratories that are tardy or delinquent in responding to the accrediting authority. A question was also asked as to whether new and renewal laboratories should both be listed.

PRIVATE SECTOR PERSPECTIVE AND SUPPLEMENTAL STATE REQUIREMENTS

Mr. Jerry Parr presented concerns on behalf of the private sector laboratories. The principal concern dealt with supplemental state requirements, especially those above and beyond the ones required for NELAP. Mr. Wilson Hershey previously identified a lengthy list of specific items known to vary among states -- reporting limits, detection limits, quality control (QC) sample frequency, the level and number of calibration standards, calculations procedures, concentration

levels of QC spikes, etc. These parameters can differ among the various programs in a state, and can obviously differ from those required by NELAP.

Mr. Parr cited Section 5.1(b) of the NELAC Standards which states that "If more stringent standards or requirements are included in a test method or by a regulation, the laboratory shall demonstrate that such requirements are met." It was agreed that if the method is an EPA method, few problems should ensue. However, if it is a state requirement, there may be major implications concerning reciprocity among the states. It was noted that a state can "wear two hats," imposing (as a accrediting authority, for instance) a certain detection limit, but then (as the client of a laboratory) require a different detection limit. It was suggested by attendees that many states are going to have difficulties buying into the full, unconditional reciprocity of NELAC with so many states setting requirements other than those stipulated by NELAC. Dr. Jackson reminded all that Section 1.6.3 clearly describes what latitude states have in setting requirements different from those of NELAP. Ms. Batterton suggested that, for a state to be approved as an accrediting authority, it may have to demonstrate some willingness to be flexible in the setting the analytical parameters of its own programs.

OTHER CONCERNS

Ms. Batterton opened the floor for discussion of any other concerns that should be brought to the attention of the Committee. A question was raised as to the cost (fee to be charged) for the review of a NELAP accrediting authority application form. When Ms. Mourrain replied that there would be no fee for the actual review of the application, many in the audience responded that this was not widely known and needs to be more clearly and widely emphasized. She also said that a state, in theory, should incur no annual expense for being an accrediting authority; it may, however, incur an expense at the time of its NELAP on-site assessment for an agreed upon portion of assessors' travel expenses.

Given that NELAP will not (and cannot) levy a fee for the review of applications, a concern was raised concerning the likelihood of long-term funding support from EPA for NELAC and NELAP. Mr. Ivan DeLoach of the EPA responded that the Agency is now receiving a strong level of funding from most of its program offices, and that this in itself is a significant accomplishment.

Many concerns remain about the details of phasing in NELAP and the phasing out of state programs.

Mr. Parr brought to the Committee's attention an item from the meeting of the NELAC Program Policy and Structure Committee on Tuesday, July 29, 1997 at the Third Annual Meeting. At that meeting, there was considerable discussion about reciprocity among states and how that reciprocity will be established. Will reciprocity be understood or implied to be automatic as a result of NELAC accreditation, or will it be done through a written document (e.g., memorandum of understanding)? It was agreed that whatever mechanism is required for two parties to establish reciprocity be allowed to happen, but that all states be genuinely committed to the unconditional reciprocity that is a cornerstone of the NELAC Standards. Committee members recognized these issues related to reciprocity as high priority items for their near-term consideration and discussion. Many concerns remain about the phasing in of NELAP and the phasing out of states' programs, and the Committee vowed to devote additional time to this issue.

The final item consisted of a plea from several individuals that private sector laboratories are an enormous key to the success of NELAP, and as such, should be encouraged to lobby their state agencies and program areas to give their support to NELAP.

Attachment A

LIST OF PARTICIPANTS
***Ad Hoc* Transition Committee**
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Name	Affiliation	Phone Numbers
Carol Batterton, Chair	Texas Natural Resources Conservation Commission	Tel: 512/239-6300 Fax: 512/239-6307 E-mail: cbattert@smtpgate.tnrcc.state.tx.us
John Anderson	Illinois EPA, Division of Laboratories	Tel: 217/782-6455 Fax: 217/602-5547 E-mail: epa6103@epa.state.il.us
Pauline Bouchard	Minnesota Department of Health	Tel: 612/623-5331 Fax: 612/623-5514 E-mail: paulinebouchard@health.state.mn.us
Charles Brokopp	Utah Department of Health	Tel: 801/584-8400 Fax: 801/584-8486 E-mail: cbrokopp@state.ut.us
Stephen Clark (absent)	USEPA Office of Water	Tel: 202/260-7159 Fax: 202/260-4383 E-mail: clark.stephen@epamail.epa.gov
Ted Coopwood (absent)	USEPA Office of Air and Radiation	Tel: 202/233-9358 Fax: 202/233-9651 E-mail: coopwood.theodore@epamail.epa.gov
Andrew Eaton	Montgomery Laboratories	Tel: Fax: E-mail:
Charles Hartwig	Florida Department of Health	Tel: 904/791-1550 Fax: 904/791-1567 E-mail: charles_hartwig@dcf.state.fl.us
Wilson Hershey (absent)	Lancaster Laboratories	Tel: 717/656-2300 Fax: 717/656-0450 E-mail: jwhershey@lancasterlabs.com
Kenneth Jackson	New York State Department of Health	Tel: 518/485-5570 Fax: 518/485-5568 E-mail: jackson@wadsworth.org

Jeanne Murrain	USEPA Office of Research and Development	Tel: 919/541-1120 Fax: 919/541-4101 E-mail: mourrain.jeanne@epamail.epa.gov
Jerry Parr	Quanterra	Tel: 303/421-6611 Fax: 303/467-9136 E-mail:jerryparr@msn.com
Ann Rosecrance	Core Laboratories	Tel: 713/329-7414 Fax: 713/895-8982
Bruce Harvey (support contractor)	Research Triangle Institute	Tel: 919/541-6573 Fax: 919/541-7386 E-mail: bwh@rti.org